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No. 04-607

In the Supreme Court of the United States

LABORATORY CORPORATION OF AMERICA HOLDINGS, DBA LABCORP, PETITIONER

v.

METABOLITE LABORATORIES, INC., ET AL.

ON PETITION FOR A WRIT OF CERTICRARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

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QUESTION PRESENTED

Respondent's patent claims a method for detecting a form of vitamin B deficiency, which focuses upon a correlation in the human body between elevated levels of certain amino acids and deficient levels of vitamin B. The method consists of the following: First, measure the level of the relevant amino acids using any device, whether the device is, or is not, patented; second, notice whether the amino acid level is elevated and, if so, conclude that a vitamin B deficiency exists. Is the patent invalid because one cannot patent "laws of nature, natural phenomena, and abstract ideas"? *Diamond* v. *Diehr*, 450 U.S. 175, 185 (1981).

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This brief is submitted in response to the order of this Court inviting the Solicitor General to express the views of the United States. In the view of the United States, the petition for a writ of certiorari should be denied.

STATEMENT

1. Deficiencies in two B vitamins, cobalamin and folate, can cause serious illnesses such as vascular disease, cognitive dysfunction, birth defects, and cancer. Once detected, however, a deficiency can be treated with vitamin supplements. Pet. App. 2a.

Scientific researchers at University Patents Inc. (UPI), the predecessor of respondent Competitive Technologies, Inc. (CTI), determined that elevated levels of total homocysteine, an amino acid, are closely associated with deficiencies in cobalamin or folate. UPI applied for and received a

patent on methods for assaying samples of body tissues to determine total homocysteine levels, as well as methods for diagnosing cobalamin and folate deficiency based on elevated total homocysteine. Pet. App. 2a-3a. The patent claim at issue here, claim 13 of United States Patent No. 4,940,658 (the '658 patent), identifies:

> A method for detecting a deficiency of cobalamin or folate in warm-blooded animals comprising the steps of:
>
> assaying a body fluid for an elevated level of total homocysteine; and
>
> correlating an elevated level of total homocysteine in said body fluid with a deficiency of cobalamin or folate.

Id. at 3a.

CTI licensed the '658 patent to respondent Metabolite Laboratories, Inc., which in turn sub-licensed the patent to the predecessor-in-interest of petitioner Laboratory Corporation of America Holdings. Physicians ordered total homocysteine assays from petitioner, which initially performed the assays under its sub-license by using the assay method set forth in the patent. In 1998, however, petitioner began using a different assay method and stopped paying royalties to Metabolite. Respondents then filed suit against petitioner for inducing patent infringement by the physicians and for breach of contract. Pet. App. 3a-4a.

2. The district court submitted the case to a jury, which found that claim 13 of the '658 patent is valid and that petitioner willfully infringed that claim and breached its contract with Metabolite. The jury assessed damages of approximately $1 million for infringement and $3.7 million for breach of contract. The court entered judgment based on the jury verdict, denied petitioner's motion for judgment as a matter of law, doubled the jury's infringement award

based on the finding of willfulness, and entered a permanent injunction against petitioner. Pet. App. 3a-4a, 34a-39a.

3. a. The Federal Circuit affirmed. Pet. App. 1a-27a. Noting that the parties focused "solely on * * * the correlating step" of claim 13, the court of appeals stressed that it did "not address the assaying step." *Id.* at 13a & n.1. "In essence," the court held, "'correlating' means to relate the presence of an elevated total homocysteine level to either a cobalamin or folate deficiency, or both * * *, and also to relate the absence of an elevated total homocysteine level to a deficiency in neither." *Id.* at 12a.

Because "[t]he record shows that physicians order assays and correlate the results of those assays," the court of appeals held that physicians who ordered assays from petitioner after petitioner stopped making royalty payments had directly infringed the patent. Pet. App. 13a. The court further concluded that substantial evidence supports the jury's finding that petitioner intended to induce such infringement because petitioner provided total homocysteine assays to physicians and encouraged the use of such assays to detect cobalamin and folate deficiency. *Id.* at 15a.

The court of appeals rejected petitioner's contentions that claim 13 is invalid on grounds of indefiniteness, lack of written description and enablement, anticipation, and obviousness. Pet. App. 15a-21a. Because "[a] patent issued by the United States Patent and Trademark Office (PTO) bears the presumption of validity under 35 U.S.C. § 282," the court explained that "[a]n accused infringer * * * must prove patent invalidity under the clear and convincing evidentiary standard." *Id.* at 15a.

In the Federal Circuit's view, petitioner did not overcome that presumption. Because claim 13 has a discernible meaning, the court concluded that it is not indefinite. Pet. App. 16a. Similarly, the court concluded that UPI enabled

the invention by disclosing all of the necessary steps, and that the written description of the claim adequately demonstrated that the inventors possessed the invention at the time of the original filing. *Id.* at 17a-18a. Because the prior art in the record did not specifically disclose that total homocysteine is correlated with B vitamin deficiency, the court further concluded that claim 13 was neither anticipated by the prior art nor obvious. *Id.* at 18a-20a.

Finally, the court of appeals affirmed the judgment of the district court on a variety of other points not at issue here, including liability for breach of contract, enhancement of damages for infringement, and injunctive relief. Pet. App. 23a-27a. It did not determine whether the patent claims unpatentable subject matter, because petitioner had not challenged claim 13's validity on that ground.

b. Judge Schall concurred in part and dissented in part. Pet. App. 28a-33a. He "agree[d] with the majority's conclusions with respect to validity" of the patent, but construed claim 13 more narrowly than the majority. *Id.* at 28a. Because "[t]he plain language of the claim requires 'elevated' levels of homocysteine," Judge Schall concluded that claim 13 is infringed only when a test reveals elevated levels, not when it reveals normal or low levels. *Id.* at 30a.

c. The court of appeals denied a petition for rehearing and rehearing en banc. Pet. App. 40a-41a.

DISCUSSION

This Court requested the views of the United States limited to the question whether claim 13 of the '658 patent is "invalid because one cannot patent 'laws of nature, natural phenomena, and abstract ideas.'" 125 S. Ct. 1413 (2005) (quoting *Diamond* v. *Diehr*, 450 U.S. 175, 185 (1981)). Claim 13 describes more than a natural phenomenon, as it does not merely recite a natural relationship between ele-

vated total homocysteine and deficiencies in the B vitamins, but also claims a diagnostic method based on that relationship—assaying for total homocysteine in order to determine cobalamin or folate deficiency. Whether that application of the natural relationship is patentable may depend in part on facts that are not well developed in the record, in large measure because the validity of claim 13 under the natural phenomenon doctrine was neither pressed nor passed upon below. The petition should therefore be denied.

A. THE PATENT CLAIM APPEARS TO INVOLVE AN UNPATENTABLE NATURAL PHENOMENON

1. The scope of patentable subject matter is generally quite broad. "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor" if the other conditions for patentability, such as novelty and non-obviousness, are satisfied. 35 U.S.C. 101. Thus, this Court has noted that "Congress intended statutory subject matter to 'include anything under the sun that is made by man.'" *Diehr*, 450 U.S. at 182 (quoting S. Rep. No. 1979, 82d Cong., 2d Sess. 5 (1952), and H.R. Rep. No. 1923, 82d Cong., 2d Sess. 6 (1952)).

"Excluded from such patent protection," however, are "laws of nature, natural phenomena, and abstract ideas." *Diehr*, 450 U.S. at 185; accord, *e.g.*, *Diamond* v. *Chakrabarty*, 447 U.S. 303, 309 (1980); *Parker* v. *Flook*, 437 U.S. 584, 589 (1978); *Gottschalk* v. *Benson*, 409 U.S. 63, 67-68 (1972); *Funk Bros. Seed Co.* v. *Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948); *Mackay Radio & Tel. Co.* v. *Radio Corp. of Am.*, 306 U.S. 86, 94 (1939). "A principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclu-

sive right." *Le Roy* v. *Tatham*, 55 U.S. (14 How.) 156, 175 (1853); see *Rubber-Tip Pencil Co.* v. *Howard*, 87 U.S. (20 Wall.) 498, 507 (1874); *O'Reilly* v. *Morse*, 56 U.S. (15 How.) 62, 116 (1853). Instead, such "manifestations of laws of nature" are "part of the storehouse of knowledge," "free to all men and reserved exclusively to none." *Funk*, 333 U.S. at 130; see *Benson*, 409 U.S. at 67 ("Phenomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work.").

Thus, "a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter" under Section 101. *Chakrabarty*, 447 U.S. at 309. "Likewise, Einstein could not patent his celebrated law that $E=mc^2$; nor could Newton have patented the law of gravity." *Ibid.* Nor can one patent "a novel and useful mathematical formula," *Flook*, 437 U.S. at 585; electromagnetism or steam power, *Morse*, 56 U.S. (15 How.) at 113-114; or "[t]he qualities of * * * bacteria, * * * the heat of the sun, electricity, or the qualities of metals," *Funk*, 333 U.S. at 130; see *Le Roy*, 55 U.S. (14 How.) at 175.

2. Claim 13 appears to *involve* such a natural phenomenon, because it asserts and relies on the existence of a naturally occurring correlation between elevated levels of total homocysteine and deficiencies in cobalamin or folate. The asserted natural relationship between elevated total homocysteine and deficiencies in the B vitamins appears to be an unpatentable "principle in natural philosophy or physical science," *Morse*, 56 U.S. (15 How.) at 116, just as the relationship between energy, mass, and the speed of light discovered by Einstein ($E=mc^2$), and the relationship between force of attraction, mass, and distance discovered by Newton (the law of gravity), are unpatentable natural phenomena. See *Chakrabarty*, 447 U.S. at 309. To the ex-

tent that the relationship is no more than an observable, naturally occurring fact of human physiology, it is also analogous to observations of the properties of bacterial strains and metals, which this Court has held to be unpatentable. See *Funk*, 333 U.S. at 130.

B. THE RECORD MAY NOT BE SUFFICIENTLY DEVELOPED TO PERMIT AN ASSESSMENT OF THE PATENT CLAIM'S VALIDITY

Determining whether claim 13 *involves* a phenomenon of nature is only the beginning of the inquiry, however, because "[i]t is now commonplace that an *application* of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection." *Diehr*, 450 U.S. at 187; accord *Flook*, 437 U.S. at 590 ("[A] process is not unpatentable simply because it contains a law of nature."); *Benson*, 409 U.S. at 67; *Funk*, 333 U.S. at 130; *Mackay*, 306 U.S. at 94; *Rubber-Tip Pencil Co.*, 87 U.S. (20 Wall.) at 507; *Le Roy*, 55 U.S. (14 How.) at 175. "[A] claim drawn to subject matter otherwise statutory does not become non-statutory simply because it uses a mathematical formula" or other scientific principle. *Diehr*, 450 U.S. at 187. Instead, "[w]hile a scientific truth, or the mathematical expression of it, is not a patentable invention, a novel and useful structure created with the aid of knowledge of scientific truth may be." *Id.* at 188 (quoting *Mackay*, 306 U.S. at 94).

1. This case involves a patent on a process, as opposed to a product, and "[t]he line between a patentable 'process' and an unpatentable 'principle' is not always clear." *Flook*, 437 U.S. at 589. In general, however, the "[t]ransformation and reduction of an article 'to a different state or thing' is the clue to the patentability of a process claim that does not include particular machines." *Diehr*, 450 U.S. 184 (quoting

Benson, 409 U.S. at 70); see *Flook*, 437 U.S. at 588-589 & n.9; *Cochrane* v. *Deener*, 94 U.S. 780, 787-788 (1876).

Even when a patent purports to apply a phenomenon of nature as part of a patentable process, the inquiry is not over. "The rule that the discovery of a law of nature cannot be patented rests, not on the notion that natural phenomena are not processes, but rather on the more fundamental understanding that they are not the kind of 'discoveries' that the statute was enacted to protect." *Flook*, 437 U.S. at 593. Thus, it is necessary "to determine what type of discovery is sought to be patented." *Ibid.*

For example, the prohibition against patenting natural phenomena "cannot be circumvented by attempting to limit the use of [a law of nature] to a particular technological environment," *Diehr*, 450 U.S. at 191, such as by attempting to patent the use of electromagnetism in communications, or the use of steam power in transportation. *Morse*, 56 U.S. (15 How.) at 112-113; accord *Flook*, 437 U.S. at 590, 594. Nor can one patent a process that comprises every "substantial practical application" of a law of nature, because such a patent "in practical effect would be a patent on the [law of nature] itself." *Benson*, 409 U.S. at 71-72; cf. *Diehr*, 450 U.S. at 187 (stressing that patent applicants in that case did "not seek to pre-empt the use of [an] equation," but instead sought only to "foreclose from others the use of that equation in conjunction with all of the other steps in their claimed process").

Such limitations on process patents are important because without them, "a competent draftsman [could] evade the recognized limitations on the type of subject matter eligible for patent protection." *Diehr*, 450 U.S. at 192; accord *Flook*, 437 U.S. at 590, 593. Only "when a claim containing a [law of nature] implements or applies that [law] in a structure or process which, when considered as a whole,

is performing a function which the patent laws were designed to protect," does "the claim satisf[y] the requirements of § 101." *Diehr*, 450 U.S. at 192.

2. The record is not sufficiently developed to permit comprehensive consideration of the question whether claim 13 satisfies the subject matter requirements of Section 101. "In determining the eligibility of respondents' claimed process for patent protection under § 101, their claims must be considered as a whole." *Diehr*, 450 U.S. at 188; accord *Flook*, 437 U.S. at 594 & n.16. Taken as a whole, claim 13 sets forth a two-step method comprised of assaying a sample of bodily fluid for total homocysteine and then using the results of that assay in determining whether the sample indicates a cobalamin or folate deficiency.

Because petitioner did not argue below that claim 13 attempts to claim non-patentable subject matter and is therefore invalid under Section 101 (see pp. 15-16, *infra*), the courts did not focus on the term "assay" or otherwise address claim 13 "as a whole." Indeed, the lower courts did not interpret the claim term "assay" at all. See Pet. App. 13a. Assaying is, however, generally understood to refer to "[t]he quantitative analysis of a substance to determine the proportion of some valuable or potent constituent." *Larousse Dictionary of Science and Technology* 64 (Peter M.B. Walker ed., 1995). It is likely that all known methods of conducting such analysis of total homocysteine entail significant physical or chemical alteration of a sample of blood or other bodily fluid. The patent at issue here, for example, sets forth specific methods of assaying for homocysteine that entail substantial physical and chemical manipulation of a sample through the following steps:

1. preparing serum from a blood sample;
2. adding a reducing reagent and heating the serum;
3. separating and discarding proteins from the serum, in part through centrifuging;
4. removing salt ions by running the sample through an ion exchange column;
5. collecting and drying the fractions that contain homocysteine;
6. adding N-methyl-N-(t-butyldimethylsilyl) trifluoroacetamide to the sample;
7. centrifuging and drying the sample; and
8. injecting the sample into a gas chromatograph with a mass spectrometer.

C.A. App. 914-915. Other assay methods described in the record likewise require substantial chemical processing. See Pl. Tr. Exh. 205; Def. Tr. Exhs. JP, BT. Considered as a whole, therefore, the claimed process appears to entail the "[t]ransformation and reduction of an article 'to a different state or thing,'" *Benson*, 409 U.S. at 70, but the record is not fully developed on that point, and it is at least possible that other methods of measuring total homocysteine levels would not involve the transformation of matter.

The record is also not well developed on the question whether the process claimed in claim 13 comprises every "substantial practical application" of the natural relationship between elevated total homocysteine and deficiencies in the B vitamins. See *Benson*, 409 U.S. at 71-72; p. 8, *supra*. Indeed, there appears to be nothing in the record that directly addresses the question whether there are other practical applications that qualify as "substantial" within the meaning of *Benson*.

3. If the claim necessarily involved the transformation of matter and did not comprise every substantial practical application of a natural phenomenon, the next question would be whether compliance with those criteria alone would suffice to bring the claim within the scope of patentable subject matter under Section 101.

a. At least before this Court decided *Diehr*, *supra*, the answer would appear to have been no. In *Flook*, this Court held that "the discovery of [a natural] phenomenon cannot support a patent unless there is some other *inventive* concept in its application." 437 U.S. at 594 (emphasis added). *Flook* therefore held that an applicant could not patent a process that consisted of three steps: measuring temperature during a catalytic conversion process; calculating an "alarm limit" pursuant to a mathematical algorithm based in part on the temperature; and updating the alarm limit based on the result of that calculation. *Id.* at 585. Although that process "implement[ed] a principle in some specific fashion," it was unpatentable because the natural algorithm—"[t]he only novel feature of the method"—merely "reveals a relationship that has always existed." *Id.* at 585, 593 & n.15. This Court explained that "once th[e] algorithm is assumed to be within the prior art, the application, considered as a whole, contains no patentable invention." *Id.* at 594. Instead, the patent claim was merely "comparable to a claim that the formula $2\pi r$ can be usefully applied in determining the circumference of a wheel." *Id.* at 595.

Under *Flook*, therefore, an applicant could not claim patentable subject matter merely by setting forth a method that transformed matter and that did not claim all substantial practical applications of a natural phenomenon. Instead, the claim, considered as a whole, also had to contain some inventive aspect other than the natural phenomenon itself. 437 U.S. at 594-595 & n.16; accord *Funk*, 333 U.S. at

132 (holding patent on mixed inoculant invalid because "once nature's secret of the non-inhibitive quality of certain strains of the species of Rhizobium was discovered, the state of the art made the production of a mixed inoculant a simple step * * * not the product of invention").

b. This Court's subsequent decision in *Diehr*, *supra*, appears to have taken a broader view of patentable subject matter than some language in *Flook* might have been read to suggest, and it has been viewed as being in tension with *Flook*. In *Diehr*, this Court held that although one cannot patent a mathematical formula, a multi-step process for curing synthetic rubber that made use of such a formula was patentable. 450 U.S. at 186-187. The Court explained that "when a claim containing a mathematical formula implements or applies that formula in a structure or process which, when considered as a whole, is performing a function which the patent laws were designed to protect (*e.g.*, transforming or reducing an article to a different state or thing), then the claim satisfies the requirements of § 101." *Id.* at 192. In so holding, the Court stated that the novelty of an invention is "of no relevance in determining whether the subject matter of a claim falls within the § 101 categories of potentially patentable subject matter." *Id.* at 188-189; see *id.* at 190 ("[W]hether a particular invention is novel is 'wholly apart from whether the invention falls into a category of statutory subject matter.'") (quoting *In re Bergy*, 596 F.2d 952, 961 (C.P.P.A. 1979), vacated as moot, 444 U.S. 1028 (1980)).

The *Diehr* Court reconciled its analysis with *Flook* on the ground that *Flook* "stand[s] for no more than [the] long-established principles" that "laws of nature, natural phenomena, and abstract ideas" are not patentable subject matter. 450 U.S. at 185. The Court stated that *Flook* involved an attempt to patent only a mathematical formula,

because although the patent claims were drawn to a method for computing an alarm limit based on several variables, they did not explain how to determine those variables, and did not disclose other matters regarding the use of the formula. *Id.* at 186-187 & n.10. Although the claimed method in *Flook* involved the "insignificant post-solution activity" of triggering an alarm based on the result of the calculations, the *Diehr* Court concluded that such activity "will not transform an unpatentable principle into a patentable process." *Id.* at 191-192 & n.14. By contrast, the patent applicants in *Diehr* did not seek to patent a mathematical formula or other natural phenomenon. Rather, they sought "patent protection for a process of curing synthetic rubber." *Id.* at 187.

c. The Federal Circuit's predecessor was strongly critical of *Flook*'s reasoning even before this Court decided *Diehr*. See *In re Bergy*, 596 F.2d at 965-966; see also *Diehr*, 450 U.S. at 204 (Stevens, J., dissenting) (observing that "in general *Flook* was not enthusiastically received by that court"); *id.* at 205 (stating that the lower court's reading of *Flook*, "although entirely consistent with the lower court's expansive approach to § 101 during the past 12 years[,] trivializes the holding in *Flook*"). The Federal Circuit later concluded that *Flook* had been "in part superseded" by *Diehr*. *Arrhythmia Research Tech., Inc.* v. *Corazonix Corp.*, 958 F.2d 1053, 1057 n.4 (1992); see *AT&T* v. *Excel Communications, Inc.*, 172 F.3d 1352, 1356 (Fed. Cir.) (stating that *Diehr* "expressly limited" *Flook*, and thereby "supported and enhanced th[e] effort" of the Federal Circuit's predecessor to "overturn[] some of the earlier limiting principles regarding § 101"), cert. denied, 528 U.S. 946 (1999).

According to the Federal Circuit, *Diehr* and *Flook* taken together stand only for "a rather straightforward

concept, namely, that certain types of mathematical subject matter, standing alone, represent nothing more than *abstract ideas* until reduced to some type of practical application, and thus that subject matter is not, in and of itself, entitled to patent protection." *In re Alappat*, 33 F.3d 1526, 1543 (1994). At least in the context of mathematical algorithms, therefore, the Federal Circuit has concluded that the proscription against patenting natural phenomena "is narrowly limited to mathematical algorithms *in the abstract*." *AT&T*, 172 F.3d at 1356 (emphasis added). More broadly, the Federal Circuit views an invention as not patentable if "the claimed subject matter as a whole is a disembodied mathematical concept representing nothing more than a 'law of nature' or an 'abstract idea,'" but views an invention as generally patentable if "the mathematical concept has been reduced to some practical application rendering it 'useful.'" *Id.* at 1357; accord *Alappat*, 33 F.3d at 1553-1554; *State St. Bank & Trust Co.* v. *Signature Fin. Group, Inc.*, 149 F.3d 1368, 1373 (Fed. Cir. 1998), cert. denied, 525 U.S. 1093 (1999).

Since this Court decided *Diehr* almost 25 years ago, PTO has generally followed the Federal Circuit's understanding that *Diehr* substantially limited *Flook*, and has issued numerous patents based on that understanding—including patents on medical diagnostic methods, other types of diagnostic and testing procedures, and computer-related processes. A decision overturning PTO's approach could call into question a substantial number of patent claims and undermine the settled expectations of numerous participants in technology-based industries. As explained below, this case does not provide an appropriate

vehicle for examining such a fundamentally important issue.*

C. THIS CASE DOES NOT PROVIDE AN APPROPRIATE VEHICLE FOR RESOLVING THE COURT'S QUESTION

This case does not provide a suitable vehicle for considering the question posed by this Court because petitioner failed either to preserve that issue in the lower courts or to develop a complete record, and the correct resolution of this case might not turn on the choice of legal standard in any event.

1. a. Petitioner did not challenge the validity of claim 13 under the natural phenomenon doctrine in either of the lower courts, and neither of those courts addressed the question. Indeed, petitioner did not mount any challenge, under any theory, to the patentability of the claimed subject matter under Section 101. Instead, petitioner argued that claim 13 is invalid for indefiniteness, lack of written description, lack of enablement, anticipation, and obviousness. Pet. Corr. C.A. Br. 38-52.

In the court of appeals, petitioner did allude to the natural phenomenon argument in the course of arguing that claim 13 is indefinite because it does not describe the "correlation" step with sufficient specificity. Pet. Corr. C.A. Br.

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* Of course, many medical and diagnostic procedures are patentable under the reasoning of either *Flook* or *Diehr* because they apply laws of nature in inventive ways. For example, the patent at issue here claims a series of assay methods whose validity has never been challenged, in part because they provide inventive ways of measuring substances in bodies. See C.A. App. 929. The number of patent claims that would be invalidated by a reversal of the Federal Circuit's understanding of *Flook* and *Diehr* is difficult to predict, and would depend in part on the rule of law adopted by this Court. At a minimum, however, a paradigm shift in the way PTO and the lower courts have viewed *Diehr* would engender substantial uncertainty.

41. In particular, petitioner noted in passing that if its indefiniteness challenge were rejected, respondent CTI "would improperly gain a monopoly over a basic scientific fact rather than any novel invention of its own. The law is settled that no such claim should be allowed." *Ibid.* (citing *Diehr*, 450 U.S. at 185). Petitioner advanced that cursory argument solely in support of its indefiniteness challenge, however, not as a separate challenge under Section 101.

Moreover, respondents correctly noted in their brief below that even if petitioner were to contend that "the claim is directed toward non-patentable subject matter under § 101 * * * [s]uch an argument is an affirmative defense that is waived as never pleaded and never tried." Resp. C.A. Br. 71. Petitioner did not respond to that point (or otherwise pursue a claim under the natural phenomenon doctrine) in its reply brief, and the court of appeals understandably refrained from addressing the issue. Because the natural phenomenon question was neither properly presented nor passed upon below, review should be denied. See, *e.g.*, *Adarand Constructors, Inc.* v. *Mineta*, 534 U.S. 103, 109 (2001); *Glover* v. *United States*, 531 U.S. 198, 205 (2001).

b. To be sure, this Court has inherent discretion to overlook petitioner's failure to raise the issue in the lower courts, particularly in light of the fact that the brief in opposition does not call the Court's attention to the waiver. See Sup. Ct. R. 15.2. Respondents should not, however, be faulted for failing to raise a waiver objection to an issue that petitioner had not squarely raised. The petition raised the natural phenomenon issue only indirectly, as support for the claims that petitioner should not have been held liable for induced infringement and that the patent is indefinite, insufficiently described, and non-enabling. See Pet. 18, 23-26. Because the petition did not raise an independent claim

resting on the natural phenomenon doctrine, respondents should not be charged with waiving their procedural objections to such a claim.

2. Moreover, because the parties did not litigate the natural phenomenon issue below, the record is not well developed on the questions relevant to resolving that issue. As a result, it may not be possible to determine whether claim 13 is valid, or even to determine whether the choice of legal standard would ultimately matter in this case.

The patent is entitled to a presumption of validity, and petitioner bears the burden of rebutting that presumption with clear and convincing evidence. See 35 U.S.C. 282; Pet. App. 15a-16a. The record does not adequately address multiple issues potentially relevant to claim 13's validity under Section 101, including whether assaying for total homocysteine necessarily entails the transformation and reduction of an article to a different state or thing, and whether the claimed process impermissibly comprises every substantial practical application of the natural relationship between elevated total homocysteine and deficiencies in the B vitamins. See pp. 9-10, *supra*. If the latter question were answered in the affirmative, for example, claim 13 would be invalid under any reading of this Court's precedents. See *id.* at 8.

The record also may not be fully developed on the question whether the patent claim involves an inventive aspect other than a natural phenomenon. If it does involve such an aspect and the other requirements discussed above are satisfied, it is valid even under *Flook*, regardless of whether or to what extent *Diehr* limited *Flook*.

Significantly, the question whether the patent claim involves an inventive aspect other than a natural phenomenon could conceivably depend in part on the construction of the claim, and the lower courts did not construe the claim

with that concern in mind. Although courts will not rewrite patents to preserve their validity, truly ambiguous patents are construed so as to preserve their validity in appropriate cases. *Liebel-Flarsheim Co.* v. *Medrad, Inc.*, 358 F.3d 898, 911 (Fed. Cir.), cert. denied, 125 S. Ct. 316 (2004). Thus, if petitioner had relied on *Flook*'s inventiveness requirement, the parties and the courts might have approached the claim construction exercise differently.

For example, the question posed by this Court assumes that the patent claim requires only that one determine a person's total homocysteine level, and then "notice whether [that] level is elevated and, if so, conclude that a vitamin B deficiency exists." 125 S. Ct. at 1413. That interpretation of the patent claim is consistent with the Federal Circuit's holding that the claim term "correlate" means "to relate the presence of an elevated total homocysteine level to either a cobalamin or folate deficiency, or both * * *, and also to relate the absence of an elevated total homocysteine level to a deficiency in neither." Pet. App. 12a; see *id.* at 8a ("The claim only requires association of homocysteine levels with vitamin deficiencies.").

As petitioner has argued (Pet. 19 n.11), however, a total homocysteine test, by itself, may not be sufficient to determine cobalamin or folate deficiency. Instead, the patent specification appears to contemplate that additional testing could occur. See C.A. App. 911. The specification explains that although elevated total homocysteine may indicate either cobalamin or folate deficiency, additional testing can reveal *which* of the B vitamins is deficient. See *ibid.* Thus, there is at least some possibility that the correlation step might be construed to entail a more involved medical diagnosis, beyond the simple mental step envisioned by the court of appeals' decision and this Court's question.

If so, the argument that the patent claim entails an inventive aspect other than a natural phenomenon would be strengthened. But because of *petitioner's* failure to rely on *Flook*'s inventiveness requirement below (or to raise any objection to patentability under Section 101), *respondents* had no incentive to argue in favor of a limiting construction of the patent, and the lower courts had no occasion to determine whether the patent could or should be read narrowly in light of that consideration. That failure to develop the contours of the claim in the context of the natural phenomenon issue is significant. As *Flook* explained and the dissent in *Diehr* repeatedly observed, the critical starting point in determining the validity of a claim for purposes of the natural phenomenon doctrine "is an understanding of what the inventor claims to have discovered." *Diehr*, 450 U.S. at 205 (Stevens, J., dissenting); accord *id.* at 193-194; *Flook*, 437 U.S. at 593 (noting that it is necessary "to determine what type of discovery is sought to be patented").

To be sure, the construction of claim 13 might not ultimately be relevant to its validity, depending upon both the rule of law applied by this Court and the outcome of full-fledged claim construction proceedings undertaken with an eye toward the considerations discussed above. But if this Court were to consider reevaluating almost a quarter-century of administrative practice and lower court jurisprudence, it should do so based on a full record in a case where the issue was properly raised, litigated, and decided below.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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